METHOD FOR KEEPING THE QUALITY OF AQUEOUS PARENTERAL SOLUTION OF THROMBOMODULIN IN STORAGE AND DISTRIBUTION

Patent Number: EP1029548
Publication date: 2000-08-23

Inventor(s): MURATA TOMOYO (JP); YOKOZAWA AKIRA (JP); YUI MASAKI (JP); SHIMIZU

HIROTOMO (JP); TSURUTA KAZUHISA (JP)

Applicant(s): ASAHI CHEMICAL IND (JP)

Requested

Patent: <u>EP1029548</u>

Application

Number: EP19980947842 19981013

Priority Number (s):

IPC Classification: A61K38/36; A61K47/00; A61K9/00

EC Classification: A61K47/44, A61K38/36, A61K47/02, A61K47/12, A61K47/26, C07K14/745B

Equivalents: AU729876, AU9460398, CA2306206, WO9918994

Cited Documents: <u>WO9516640</u>; <u>JP6321805</u>

Abstract

WO1998JP04609 19981013; JP19970281659 19971015; JP19970308523 19971111

A method for keeping the quality of an aqueous parenteral solution of thrombomodulin which is not in a frozen or freeze-dried state but in a liquid form in storage and distribution, characterized in that the aqueous thrombomodulin solution containing an effective amount of soluble thrombomodulin and a buffer component exhibiting a buffering activity in a pH range of 5 to 7.0 has a pH of 5 to 7.0 and that (a) the aqueous thrombomodulin solution further contains a surfactant and is in a state aseptically filled into a case or (b) the aqueous thrombomodulin solution is in the form of a prefilled syringe preparation produced by aseptically filling the thrombomodulin solution into a syringe substantially without any empty space. This method enables the storage and distribution of an aqueous parenteral solution of thrombomodulin in a liquid state for a prolonged period and makes it possible to provide an aqueous parenteral solution which is excellent in long-term stability and shaking stability and can save the trouble of dissolving in use.

Data supplied from the esp@cenet database - 12